DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 5, 2016

COPAN ITALIA S.P.A.
C/O TINA WU
REGULATORY PROJECT MANAGER
ICON PLC
62 FOREST STREET, SUITE 300
MARLBOROUGH, MA 01752

Re: K142094
Trade/Device Name: Copan FecalSwab Collection, Transport and Preservation System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport culture medium
Regulatory Class: Class I
Product Code: JSM, LIO
Dated: July 30, 2014
Received: August 1, 2014

Dear Dr. Wu:

This letter corrects our substantially equivalent letter of April 10, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ribhi Shawar -S

For Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142094

Device Name
Copan FecalSwab Collection, Transport and Preservation System

Indications for Use *(Describe)*
The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Copan FecalSwab Collection, Transport and Preservation System

1. APPLICANT/SPONSOR

Copan Italia S.p.A.
Via F. Perotti 10
25125 Brescia, Italy

Contact Person: Elisabetta Zanella
Telephone: +39 030 2687247

Date Prepared: April 8, 2015

2. DEVICE

Proprietary Name:	Copan FecalSwab Collection, Transport and Preservation System
Common/Usual Name:	Collection and Transport Device
Classification Name:	Culture Media, Non-Propagating Transport
Classification Panel:	Microbiology
Classification Regulation:	866.2390
Product Code:	JSM, LIO
Class:	1

3. PREDICATE DEVICE

- Copan Venturi Transystem Cary-Blair Medium - K946286

4. DEVICE DESCRIPTION

The Copan FecalSwab Collection, Transport and Preservation System (Copan FecalSwab System) is supplied in a sterile collection kit format. Each collection kit consists of a package containing a plastic screw-cap tube with conical shaped bottom filled with 2ml of FecalSwab transport and preservation medium and a specimen collection swab that has a tip flocked with soft nylon fiber.

The FecalSwab transport and preservation medium is a maintenance medium comprised of: Chloride salts, Sodium salts, Phosphate buffer, L-Cysteine and Agar. The medium is designed to maintain the viability of enteric pathogenic bacteria during transit to the testing laboratory.

The nylon flocked specimen collection swabs provided with the Copan FecalSwab Collection, Transport and Preservation System have a solid plastic shaft with a molded breakpoint site.

5. INTENDED USE

The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.

Indications for Use

The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

The Copan FecalSwab System is substantially equivalent to the predicate specimen collection and transport device. The Copan FecalSwab System and the predicate device are similar in intended use and overall function.

The proposed and predicate devices are single-use products intended for the collection and transport of clinical specimens containing enteric pathogenic bacteria. The Copan FecalSwab and Copan Venturi Transystem are both offered in collection kit format with specimen collection swab for rectal sampling. The specimen collection swab can also be used as a transferring tool for stool specimens.

Table 5-1. Side-by-Side Comparison of Copan fecalSwab Collection, Transport and Preservation System and Predicate Device

Characteristics	Copan FecalSwab Collection, Transport and Preservation System	Copan Venturi Transystem Cary-Blair Medium (Copan Diagnostics Inc.)
Regulatory Status	New Device	K946286
Product Code	JSM, LIO	JSM
Intended Use	The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.	The Copan Venturi Transystem Cary-Blair product is a sterile, single use specimen collection chamber intended to preserve the viability of microorganisms after their collection and during their transport from the collecting area to the laboratory. These devices are intended for the collection, transport and preservation of clinical specimens for bacteriological examination.
Anatomical Sites	Rectal Specimen	Rectal Specimen

Characteristics	Copan FecalSwab Collection, Transport and Preservation System	Copan Venturi Transystem Cary-Blair Medium (Copan Diagnostics Inc.)
Performance	Viability of target micro-organisms up to 48 hours at room temperature and 72 hours at 2°C-8°C. For *C. difficile*, up to 48 hours at 2 – 8 °C and up to 24 hours at 20 – 25 °C.	Viability of target micro-organisms up to 48 hours at room temperature
Microorganisms supported	Enteric pathogenic bacteria	Enteric pathogenic bacteria
Microorganisms tested	*Echerichia coli* *Echerichia coli O157:H7* *Salmonella typhimurium* *Shigella sonnei* *Campylobacter jejuni* *Yersinia enterocolitica* *Vibrio parahaemoliticus* *Enterococcus faecalis vancomycin resistant (VRE)* *Clostridium difficile*	*Echerichia coli* *Shigella flexneri* *Campylobacter jejuni* *Yersinia enterocolitica*
Product Configuration	Film-film peel-pouch containing 1 tube filled with 2 ml of liquid medium and 1 regular size flocked swab	Film-film peel-pouch containing 1 tube filled with 5 ml of gel medium and 1 regular size rayon (viscose) swab
Medium Formulation	Chloride salts Sodium salts Phosphate buffer L-Cysteine Agar Water	Sodium Chloride Calcium Chloride Disodium Hydrogen Phosphate Sodium Thioglycolate Bacteriological Agar Water
pH	6.90 – 7.50	6.90-7.50
Storage Temperature	5-25ºC	5-25°C
Medium Volume	2 ml	5 ml
Ratio between sample and elution volume	80 mg/ml	Not Applicable
Container	Tube; Plastic, conical bottom	Tube; Plastic
Collection tool	Flocked Swab	Viscose Swab
Swab Tip	Flocked nylon	Viscose
Swab Shaft	Plastic	Plastic
Shelf Life	15 months	20 months
Biocompatible	Yes	Yes
Sterility	Gamma Radiation – SAL 10^{-6}	Gamma Radiation – SAL 10^{-6}

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Studies were conducted to evaluate the performance characteristics of the Copan FecalSwab System components as well as the complete FecalSwab collection kit formats.

Recovery

Bacterial recovery studies were performed using the Copan FecalSwab and the predicate device to determine the ability of the product to maintain viability of various strains of enteric pathogenic bacteria.

Table 5-2. Summary of Results for Bacterial Recovery in PBS

Organism*	Holding Temperature	AVERAGE CFU RECOVERED (N = 3 LOTS TESTED) Time 0 hrs	Time 6 hrs	Time 24 hrs	Time 48 hrs	Time 72 hrs	T=48HRS -72 HRS LOG REDUCTION (-) OR LOG INCREASE (+)
***Escherichia coli* ATCC 25922**	2-8°C	1.07E+02	1.12E+02	8.46E+01	8.31E+01	7.29E+01	**-0.17**
	20-25°C	1.07E+02	1.35E+02	1.32E+03	5.72E+03	NA	**1.73**
***Escherichia coli O157:H7* ATCC 700728**	2-8°C	8.99E+01	1.01E+02	1.04E+02	1.07E+02	1.04E+02	**0.06**
	20-25°C	8.99E+01	1.28E+02	2.57E+02	4.12E+03	NA	**1.66**
***Salmonella typhimurium* ATCC 14028**	2-8°C	1.38E+02	1.41E+02	1.59E+02	1.58E+02	9.70E+01	**-0.15**
	20-25°C	1.38E+02	5.84E+02	2.27E+03	9.72E+03	NA	**1.85**
***Shigella sonnei* ATCC 12022**	2-8°C	1.27E+02	1.26E+02	4.16E+01	1.46E+02	1.16E+02	**-0.04**
	20-25°C	1.27E+02	4.76E+02	1.91E+03	9.67E+03	NA	**1.88**
***Clostridium difficile* ATCC 9689**	2-8°C	4.42E+01	2.26E+01	6.03E+00	6.30E-01	NA	**-1.85**
	20-25°C	4.42E+01	1.77E+01	5.30E-01	NA	NA	**-1.92**
***Vibrio parahaemolyticus* ATCC 17802**	2-8°C	2.00E+02	1.78E+02	1.76E+02	1.68E+02	1.54E+02	**-0.11**
	20-25°C	2.00E+02	2.22E+02	1.62E+03	1.58E+04	NA	**1.90**
***Enterococcus faecalis vancomicin resistant (VRE)* ATCC 51299**	2-8°C	1.68E+02	1.67E+02	1.52E+02	4.38E+02	1.16E+02	**-0.16**
	20-25°C	1.68E+02	1.70E+02	4.39E+02	2.26E+03	NA	**1.13**
***Yersinia enterocolitica* ATCC 9610**	2-8°C	1.17E+02	1.14E+02	1.12E+02	1.09E+02	1.04E+02	**-0.05**
	20-25°C	1.17E+02	1.72E+02	1.24E+03	9.78E+03	NA	**1.92**
***Campylobacter jejuni* ATCC 33291**	2-8°C	2.14E+02	1.66E+02	1.33E+02	8.63E+01	3.42E+01	**-0.80**
	20-25°C	2.14E+02	1.68E+02	5.83E+01	4.28E+00	NA	**-1.70**

* the organism was diluted in PBS and the pure suspension tested in studies based on CLSI M40-A2.

Table 5-3. Summary of Results for Bacterial Recovery in Fecal Matrix

Organism*	Holding Temperature	AVERAGE CFU RECOVERED (N = 3 LOTS TESTED) Time 0 hrs	Time 6 hrs	Time 24 hrs	Time 48 hrs	Time 72 hrs	T=48HRS - 72HRS LOG REDUCTION (-) OR LOG INCREASE (+)
***Escherichia coli O157:H7* ATCC 700728**	2-8°C	1.23E+02	1.37E+02	1.38E+02	1.53E+02	1.60E+02	**0.11**
	20-25°C	1.23E+02	1.34E+02	7.48E+02	7.54E+03	NA	**1.79**
***Salmonella typhimurium* ATCC 14028**	2-8°C	9.46E+01	1.05E+02	1.20E+02	1.32E+02	1.43E+02	**0.18**
	20-25°C	9.46E+01	1.17E+02	6.51E+02	6.38E+03	NA	**1.83**
***Vibrio parahaemolyticus* ATCC 17802**	2-8°C	1.11E+02	1.21E+02	1.29E+02	1.26E+02	1.36E+02	**0.09**
	20-25°C	1.11E+02	1.34E+02	1.14E+03	7.36E+03	NA	**1,82**

* the organism was diluted in fecal matrix and the suspension tested in studies based on CLSI M40-A2

Stability

Stability testing was performed on aged Copan FecalSwab products to support the 15-month expiration date. Additionally, the recommended sample fill line was established as well as the buffering capacity of the medium.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted to support this submission.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed Copan FecalSwab System and the predicate lead to a conclusion of substantial equivalence between the proposed and predicate device. A side-by-side comparison of the proposed device and predicate device is provided in the table at the end of this section.